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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,489

07/10/2003

Thomas L. Cantor

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12/05/2005

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,489

Applicant(s)

CANTOR, THOMAS L.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 22-39 and 58-83 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 60-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 22, 23, 29-37, 58, 59 and 81-83 is/are rejected.
- 7) ☒ Claim(s) 17, 18, 38 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date see below.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

4/18/05; 5/19/05, 7/7/05, 7/21/05, 8/5/05,

DETAILED ACTION

Applicant's amendment filed on 3/30/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 19-21, 40-57 are cancelled. Claims 82-83 are added.
2. Claims 1-9 and 60-80 are withdrawn from consideration.
3. Claims 10-18, 22-39, 58-59 and 81-83 are under examination.

Information Disclosure Statement

The newly submitted English Abstract of DE3347548 (German patent application) and the US 60/224396 (Hammis et al) provisional application have been received and reviewed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 10-18, 22-39, 58-59 and 81-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 10, it is not clear whether the method requires any label for determining the complex of wPTH and the antibody.

With respect to claim 25, it is not clear what is the relationship of this second antibody to the first antibody. Applicant recites the first antibody binds to an N-terminal sequence of

Art Unit: 1641

the whole PTH, whereas the second antibody binds to a portion other than this N-sequence, yet “which binds to the first antibody”. According to Figure 2-3 and 6-7, the relationship of the two antibodies does not support the claim language, i.e. first antibody binds to the second antibody. Applicant needs to clarify.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10-16, 22-37, 58 and 81-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Gao et al. (Clinica Chimica Acta 1996 Vol. 245, page 39-59).

Gao et al. developed an immunochemiluminometric assay using antibodies to detect the human parathyroid hormone (hPTH). Gao et al. teach using antibodies specific for hPTH to detect serum samples from patients for the assay (See Materials and Methods). The antibodies are specific for the N-terminal, but not able to bind to the non-whole PTH fragments, such as 4-16, 28-48, 39-84, 44-68 and 53-84 (See Abstract).

With respect to claims 11-16, Gao et al. teach using the specific antibodies, e.g. monoclonal antibodies, to detect the serum from primary hyperparathyroidism patients (See Table 3 and Case report).

With respect to claim 22-23, Gao et al. teach the non-whole PTH fragment is hPTH 4-16, 28-48, 39-84, 44-68 (See Section 3.2.2).

With respect to claim 24-28, Gao et al. teach using two antibodies, e.g. two-sites comparative immunoassay to detect the PTH in serum sample (See Introduction,

Art Unit: 1641

Abstract). Two antibodies are used by Gao et al.. One serves as a capturing antibody against 1-34, and the other as detecting antibody against 44-68 (See page 43, section 2.6).

With respect to claims 29-30, Gao et al. teach sandwich, e.g. two-site immunoassay by using two antibodies (See Materials and Methods).

With respect to claims 31-33 and 81, the immunoassay taught by Gao et al. has detection limit about 0.4 pmol/L, and exhibits a normal range of 1.3-12 pmol/L (See Abstract, page 57, second paragraph).

With respect to claims 34-35, the antibodies taught by Gao et al. recognize fragment of hPTH 39-84 and 1-34 (See Abstract) The hPTH 39-84 is a C-terminal PTH fragment (See Abstract).

With respect to claims 36-37 and 58, the immunoassay taught by Gao et al. can be used to detect bone turnover related disorder or hyperparathyroidism (See page 40, first paragraph, and page 53, Case report).

Response to Applicant's Arguments

Applicant's arguments with respect to claims 10-18, 22-39, 58-59 and 81 by references Slatopolsky and Gao et al. (II)(J. Bone Mineral Res. 2001 Vol. 16, page 605-614) have been considered but are moot in view of the new ground(s) of rejection.

35 USC 112, Second paragraph

Applicant's arguments regarding whether it is required a label in the method claim 10 to carry out the purported purpose has been considered but are not persuasive.

Art Unit: 1641

Applicant argues that besides radioactive or fluorescent label, “*other labels, e.g. enzyme or chemiluminescent labels, can be used as well. In addition, depending on the assay formats, an antibody can be labeled as in a sandwich assay format, But in other format, e.g. a competitive assay format, a label can be attached to an analyte or anylte analog*”(See Remarks, page 17, last paragraph to the first paragraph of page 18)(emphasis added). The recited method, according to what applicant explained here, does in fact need some kind of labels to perform, whether in the antibody or analytes (See the comments quoted above). Therefore, the rejection under 35 USC 112, second paragraph set forth in the previous Office Action is maintained.

Allowable Subject Matter

5. Claims 17-18 and 38-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is an examiner’s statement of reasons for allowance: no prior art teaches or fairly suggests using antibodies specifically for epitopes of PTH on 1-6, 1-8, 1-9, 1-12 or 1-15, to detect hPTH by using another antibodies specific for the non N-terminal regions of hPTH, and determining a ratio of whole PTH level and the total PTH level. The closest prior art is the Gao et al. reference (Clinica Chimica Acta 1996, Vol. 245, page 39-59) where Gao et al. teach antibodies specifically for N-terminal, yet Gao et al. do not disclose the specific N-terminal epitopes as recited in the instant claims. Furthermore, Gao et al. do not teach measuring the ratio of the whole and total PTH for the hyperparathoridism patients.

Conclusion

7. No claim is allowed.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jacob Cheu

Examiner

Art Unit 1641



November 23, 2005


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800
11/26/05